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Chapter 1
Gel

Use of conductive gel on the probe and breast is highly recommended in order that the probe will move smoothly on the breast and to improve electrical conductance between breast tissue and the probe sensors. However, conductive gels differ considerably in their properties. In particular, best results are obtained when using low viscosity gel such as:

Gamma Massage and Ultrasound gel

Manufactured by: Pharmaceutical Innovations, Inc.

Contact your local sales (or service) representative for ordering information.

Instructions for Use

See User Manual, Chapter 5, Setting up and Examination.

Chapter 2
Phantom

Description

The phantom (optional) is to be used only: (1) to insure that the relative sensitivity between sensor elements is maintained; and (2) for training purposes. It is recommended that measurements should be made on the phantom at monthly intervals.

> **Note:** Use the phantom only for training purposes or to insure that the relative sensitivity between sensor elements is maintained.
>
> The phantom is not intended for calibration purposes and is not suitable for calibration of the device.

The phantom is constructed from a polyacrylamide hydrogel shaped as a block measuring 10 x 10 x 2 cm. It comes in a special sealed container that serves for storage and measurement. The storage solution is designed to prevent contamination of the phantom during its lifetime (one year). The expiration date is written on a sticker placed on the back of the container. In case of

expiration, a replacement phantom is available upon request, contact your local sales (service) representative. On the outside of the storage container are three screws used for attaching the electrical cable.

Handling and Maintenance

In order to get the best performance from the phantom and maximize its lifetime, you must store it according to the following conditions:

- Store the phantom at room temperature (10˚C - 30˚C).
- Keep the container closed when the phantom is not in use.
- Do not expose the phantom to direct sunlight.
- Make sure the phantom is covered with solution. If needed, add distilled water.
- Do not use the phantom if signs of deterioration such as cracking, change of color or any other physical changes appear.
- At the end of its lifetime (one year) dispose of the phantom. It may be disposed of with no special precautions.

General Instructions

! Caution: Use gloves when handling the phantom for protecting the phantom against contamination.

When you make measurements on the phantom, you must connect theTS2000 source electrode to the middle screw of the phantom container (screw number 2 in the image, above). You then place the probe on the phantom to record values for capacitance and conductance. Use Table 1 below to compare measurements with the expected values. If any of the results exceed the relative values in Table 1, contact the local service person.

! Caution: Clean the probe with alcohol before and after each use.

Table 1: Standard values for PHANTOM measurements.

Probe	Min/Average	Max/Average	Sd/Average
Small (64)	>0.75	<1.25	<0.10
Large (256)	>0.75	<1.25	<0.15

Detailed Instructions

1 Turn on the TS2000 system.

2 Start a new exam by opening the Define New Exam screen (see Chapter 5, User Manual).

3 Enter exam type in the Last name and First Name fields (see **NOTE** below).

> **Note:** In order to start a new exam you must first enter a name in the Last and First Name fields on the Define New Exam screen. When you are testing the probe 256 enter ***Probe*** in the last Name field and ***256*** in the First Name field. When you are testing the probe 64 enter ***Probe*** in the last Name field and ***64*** in the First Name field.

4 Disconnect the cylindrical source electrode from its connecting cable.

5 Attach the connecting cable to the middle of the three screws outside the storage container (screw # 2).

6 Open the storage container.

> **! Caution:** Make sure that the phantom is covered with immersion fluid. If needed, add distilled water. Do not perform a measurement on the phantom unless it is covered with fluid.

7 Select a probe and place it on the upper surface of the phantom.

8 Select START, and make sure that the probe is evenly mounted on the surface of the phantom and a uniform image is obtained. You may need to move the probe a little to insure that no air bubbles remain.

9 Select RECORD, holding the probe steady until the recording stops.

10 Enter the REPLAY mode by pressing REPLAY on the toolbar.

11 Pull an ROI square over the whole image (see below).

12 Compare the relevant data to the tolerance values in table 1 (see figure below).

> **Note:** The **mean** is displayed between the two sector enlargement windows. The **standard deviation, the minimum and the maximum** are directly displayed on the image after you draw the ROI (see picture on next page).

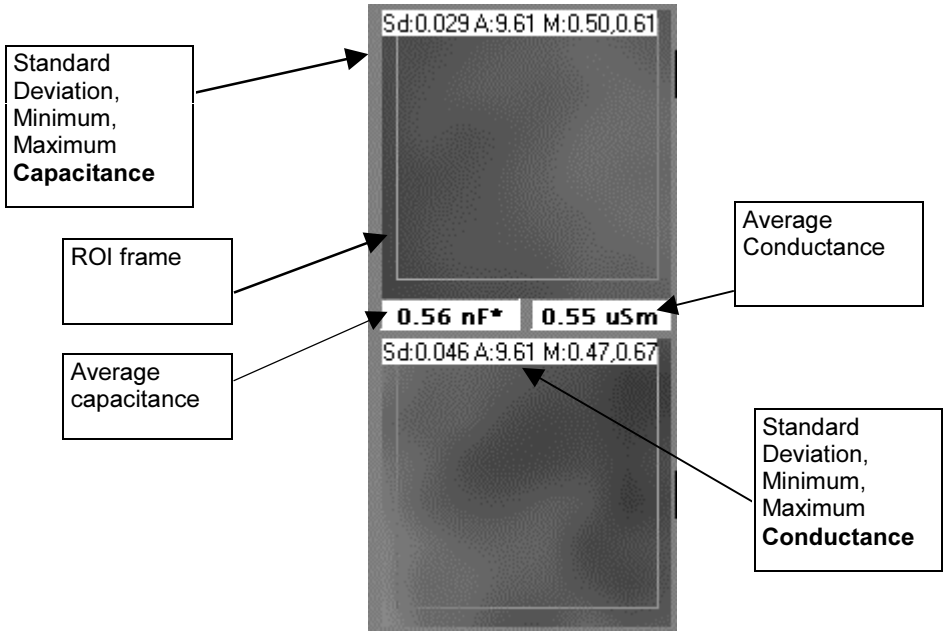
13 Repeat the process for the second probe (if applicable).

To Draw a Region of Interest (ROI)

1 Select the sector with the phantom recording by clicking the mouse.

2 Place the cursor arrow in the upper left-hand corner of the Sector Enlargement window.

3 Depress the left mouse button and drag across the Sector Enlargement window; a frame appears around the ROI in both sector enlargement windows.



To remove an ROI

1 Point the cursor to the sector enlargement window.

2 Double-click the left mouse button. The ROI disappears.

Training

The phantom may be used for obtaining an image, without applying the probe to a human subject, while training new users. As the training session can take 3 days it will be impossible to use a human subject for the whole training session. Furthermore, a human subject may not be available at all as the examiner, which is being trained, didn't schedule any patients for the training session. The use of the phantom in this case is very beneficial as the first part of the training session can be done without relying on the availability of a human subject (a patient) for explaining the basic operation of the system.

With the phantom, the trainer can demonstrate the use of the probe on a human

body and the proper acquisition technique so when the trainee finally starts working with a human subject, he is sufficiently experienced with using the system and the training on the human subject can focus on the scanning technique and not on the operation of the system and probe.

The objective of training the user on a phantom is that at the end of the first training part, the user will know how to get rid of bubbles, how to use and apply gel on the probe, how to slide the probe on the body in order to get a proper image, how to use the probe's buttons correctly in order to acquire an image and how to hold the probe steady so that good contact is maintained between the probe and the body.

The image acquired from the phantom may than be used for demonstration of further data analysis such as using the center and width controls for adjusting the contrast and brightness of the image, the use of the database for entering a new patient and then using the data for practicing the replay of a previously acquired image and the use of other features such as backup and restore.